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Doing More Good Than Harm With Children's Medications

When it comes to doctoring their children with over-the-counter (OTC) medications, some parents may not be doing too good a job, according to a panel of pediatric experts. Reviewing some 3,900 decisions about using OTC medications made over a nine-month period, the experts could give "only minimal approval" to the way 500 mothers treated their ailing youngsters. In fact, the panel felt that the mothers did only slightly more good than harm for their children. In a few cases, the mothers' choices were considered dangerous (abuse of laxatives was common).

The study, conducted at the Universities of Michigan and Rochester by Lois A. Maiman, Marshall H. Becker, and Anne W Katlic (and published in the *Journal of Community Health*, fall 1985), found that poor decisions often involved selecting the wrong medication for a child's condition. Errors involving the wrong dosage or duration of treatment were less significant. It appears that the widespread failure of adults to read the labels of OTC medicines they take themselves carries over to some extent in treating their children. Instead of reading the directions, parents often rely on that old standby: guesswork. Other studies have shown that the problem of mismedicating our children extends to prescription drugs as well.

It has been estimated that of the 13 million American children who are given medicines in any two-week period, only about half take the medicine correctly—this includes both prescription and over-the-counter (OTC) drugs. It is even more distressing when we realize that even those children who rely on prescription medications to treat serious illnesses—such as anticonvulsants for epilepsy—may not be receiving them properly.

One of the most common misuses of medication is stopping it too soon. This is especially crucial with antibiotics. Often, when the child begins to feel well, the parent thinks the infection is cured and stops giving the child the antibiotic. When this is done, there is a chance that the child will become sick again with the same bacterial infection. In the case of an anticonvulsant drug, stopping the medication may cause the child to suffer more seizures. The message here is quite clear: Use a prescribed medication for as long as the doctor recommends! In the case of antibiotics, this usually means finishing all the pills or liquid.

Another type of misuse occurs when a child simply won't take the medicine or a parent refuses to give the medicine to the child. Children refuse to take medicine for different reasons. Some have difficulty swallowing pills, some don't like the taste of liquid medicines, some are simply afraid of medicine. Parents have their own reasons for not administering a medicine: They don't approve of the side effects or don't want to administer the medicine at the scheduled time, preferring not to interrupt the child's sleep or play. Again, the child is more likely to get well if he or she is given the medicine as prescribed.

Perhaps the most dangerous misuse of medication is giving too much medicine to a child. Once again, if relying on guesswork to determine the medicine dose for a child, a parent might give too much of the drug. Parents sometimes rely on "more is better" logic, which can lead to severe reactions in many children. Or, particularly with OTC medications, they may give a child a small dose of an adult medication thinking that their child is simply a "little adult." This can be dangerous—children should not be given medicine that is not appropriate for them. Parents should carefully read the labels of OTC drugs. If a children's dosage is not given, the medication should not be given to a child until a physician is consulted.

Misuse of children's medications can also lead the doctor to make improper decisions about the child's health. For example, if a parent says that the drug prescribed is not working, the doctor may increase the dosage or prescribe another medicine. In reality, however, the child may not be recovering because the parent is giving less than the prescribed dose. If the doctor, not realizing that the problem is under-dosing, increases the prescribed dose, overdosing and all its dangers may result.

While OTC drugs generally have such a wide margin of safety that a somewhat

HE 20.4010/a:

FDA CONSUMER
A REPRINT FROM FDA CONSUMER MAGAZINE
DEPARTMENT OF HEALTH AND HUMAN SERVICES, Public Health Service, Food and Drug Administration, Office of Public Affairs, 5600 Fishers Lane, Rockville, Md. 20857

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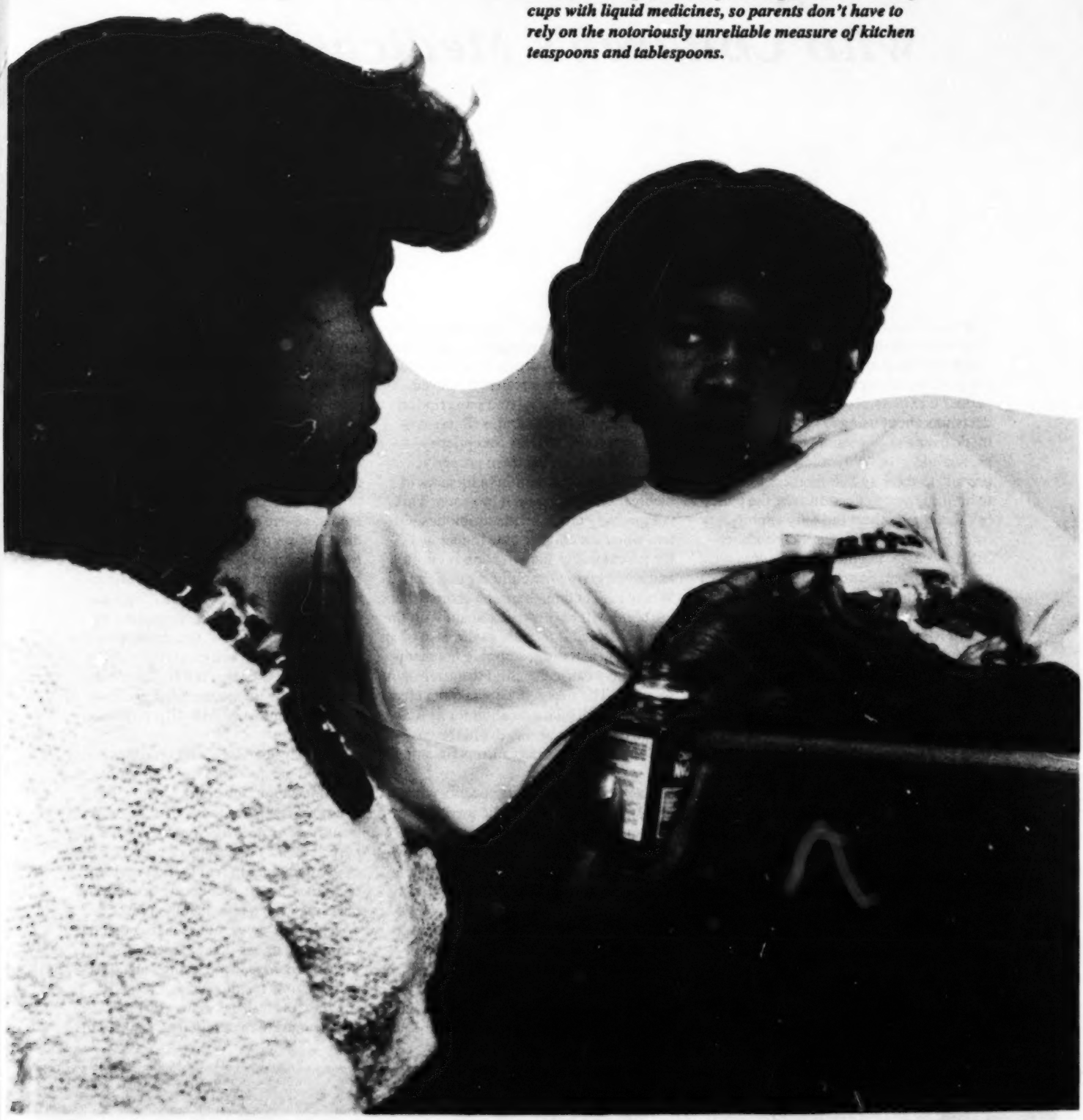
How much is enough? How much is too much? Makers of nonprescription children's medicines are working with FDA to develop more precise dosing instructions for their products. Some companies have taken other steps, such as providing calibrated dosing cups with liquid medicines, so parents don't have to rely on the notoriously unreliable measure of kitchen teaspoons and tablespoons.



excessive dose won't do much harm, sometimes a wrong dose—even of a children's drug—can lead to disaster. One case in point was the quaintly named "Sweet Spirits of Nitre," an old-time remedy for children on the market since the days before FDA had legal authority to approve new drugs before they could be sold. This unexamined product to reduce fever and relieve colic turned out to be a solution of ethyl nitrite in alcohol. Several years ago, a teaspoonful of it killed a 4-month-old infant. That teaspoonful was several times the manufacturer's recommended dose. FDA took the lethal "Sweet Spirits" off the market in 1980.

Even when parents diligently try to follow the directions on the label, the instructions are sometimes so imprecise or overly cautious that they finally ignore them. For one thing, every parent knows that there is an enormous difference between an infant and a child of 6 or 12, yet in the past many medicines didn't distinguish dosages for the different ages with the greatest possible precision. Experience may have taught some parents what recent research now confirms: that children's recommended dosages in some cases have been too low for maximum effectiveness. (Over the past several years, FDA's review of OTC drugs and their labeling has helped to improve this situation.)

Diluting Draughts of Wine

The quest for correct drug dosages for children has been going on at least since the ancient Greek physician Hippocrates recommended diluting medicinal draughts of wine for infants. Part of the challenge in today's efforts to refine dosages stems from the fact that drugs are usually tested in healthy adult volunteers who might be best able to resist unanticipated side effects. Experiments on children are usually out of the question, particularly for the relatively milder conditions that OTC remedies usually address. Consequently, pertinent test evidence involving children is hard to come by. Experience with products already on the market has to serve as a substitute.

To remedy this situation, FDA is involved in an effort to develop more precise—and, if possible, more standardized—dosage instructions for children's medications. The goal is a labeling system that is reliable and simple to follow.

At the center of the pediatric dosing issue is a debate about the best criteria for measuring the effects of drugs on the body, particularly the rapidly changing bodies of growing children. Age, though the most obvious, is only one of several determinants; weight or body surface area can be far better predictors of how an individual may respond to a certain dose of a drug. Body length allows for a rapid estimation of weight, which is particularly useful in emergency situations; moreover, since many medicines are distributed through body water rather than fat, length-based dosing avoids the risk of overdosing obese patients.

Refined Yet Simple Dosages

There's also the practical consideration of what instructions the consumer will actually be able to follow. If the refined dosage instructions are going to be used, they have to be kept simple enough for everyone to comprehend.

In laboratory conditions, many scientists agree that the most accurate way to gauge the proper dosage of a given drug for a child—or for an adult, for that matter—is to base it on the patient's body surface area. As a working norm for children's dosages, however, this ideal seems impractical. Few parents know their children's body surface area or how to calculate it. But since surface area corresponds roughly with weight, that less precise but more accessible criterion seems to be more usable.

Age is even less precise as a gauge of drug tolerance, yet it does correspond,

more or less, with a child's probable weight and body surface. The overwhelming advantage of using age in pediatric dosing is that a child's age is almost always known, more so than weight and certainly more so than body surface area. Yet some experts argue that a child's height corresponds even more closely to weight than does the child's age, thus suggesting another alternative standard.

An intriguing proposal in drug labeling for children is to list both age and weight, allowing more precise dosing of children who are either heavier or lighter than average for their age.

Some agreement seems to be forming in the medical community that a standard pediatric dosage unit one-eighth the size of the usual adult dosage could be adapted to childhood growth patterns. While this might work for tablets or capsules, liquid medicines might require more precisely calibrated dosing devices on the order of the plastic dosage cup now included with some cough-cold products. Advocates of length-based dosing note that a measuring device coded for dosages appropriate to each height range would also help avoid the imprecisions of the traditional household teaspoon, which can vary considerably in actual size. In a standard children's dosing schedule, whether based on age, weight, height, or some other formula, parents would know exactly just how many units to give their children .

Meanwhile, the responsibility for properly medicating children rests primarily with parents.

The first decision is to select the right medication; the second—equally important—is to give the proper dosage for the proper length of time, *following the package instructions.*

While modern pediatric OTC medicines are very safe, *any* drug can have bad effects if taken in excess or without regard to the instructions. The warnings on the labels should be followed unless a medical professional indicates otherwise. A product good in itself can be harmful if used inappropriately. For instance, some parents have been reported to use OTC products for prevention, giving their children regular doses of aspirin to prevent headaches or laxatives to prevent constipation. Both practices over time can be harmful. Some medications, of course, shouldn't be given to children at all, including some extra-strength combination cough-cold products, some time-release remedies, and sleeping pills. Always check the label to see whether a medicine should not be given to children.

One special warning: Aspirin—even children's aspirin—should not be given to children or teenagers suffering from or recovering from the flu, chickenpox, or other viral illness. Use of aspirin in such situations has been associated with the onset of Reye syndrome, a rare but serious—even fatal—condition.

There are nearly as many reasons why a parent doesn't properly dispense medicine to a child as there are ways to misuse medicine. Many adults do not properly dispense medicines for themselves, and this habit is simply continued when the parent dispenses medicine to a sick child. Parents should be aware that they need to be good role models. They should take the time to read and follow the medicine label directions when they are sick and pass along these good habits to their children. Children are never too young to learn about safe medicine use.

Parents should make sure they understand four important pieces of information when they give medicine to their children: (1) what the medicine is for, (2) how much to give, (3) when to give it, and (4) how long to continue giving it. If parents get the answers to these four questions from product labeling, the physician, or the pharmacist, it will go a long way towards doing more good than harm with children's medications. ■

A REPRINT FROM FDA CONSUMER MAGAZINE

REPRINTED FROM MARCH AND OCTOBER 1989 REVISED MARCH 1991 DHHS PUBLICATION NO. (FDA) 91-3182

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